

**BASIC CARE DAYTIME NIGHTTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl  
L. Perrigo Company**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----

**Amazon daytime nighttime severe cold & flu Drug Facts**

**Active ingredients (in each caplet) - Nighttime**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

**Active ingredients (in each caplet) - Daytime**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

**Purpose - Nighttime**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

**Purpose - Daytime**

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

**Uses - Nighttime**

- temporarily relieves common cold/flu symptoms:
- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- minor aches and pains

- headache
- fever
- sore throat
- runny nose and sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

### **Uses - Daytime**

- temporarily relieves common cold/flu symptoms:
- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- minor aches and pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

### **Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

### **Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for

depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

- if you have ever had an allergic reaction to this product or any of its ingredients

#### **Ask a doctor before use if you have - Nighttime**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- trouble urinating due to an enlarged prostate gland

#### **Ask a doctor before use if you have - Daytime**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

#### **Ask a doctor or pharmacist before use if you are - Nighttime**

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

#### **Ask a doctor or pharmacist before use if you are - Daytime**

taking the blood thinning drug warfarin

#### **When using this product - Nighttime**

- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

### **When using this product - Daytime**

do not use more than directed

### **Stop use and ask a doctor if - Nighttime**

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

### **Stop use and ask a doctor if - Daytime**

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

### **If pregnant or breast-feeding,**

ask a health professional before use.

### **Keep out of reach of children.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### **Directions – Nighttime and Daytime**

- take only as directed - see overdose warning
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	2 caplets with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

### **Other information - Nighttime**

- store at 20-25°C (68-77°F)

### **Other information - Daytime**

- **each caplet contains:** sodium 4 mg
- store at 20-25°C (68-77°F)

### **Inactive ingredients - Nighttime**

crospovidone, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

### **Inactive ingredients - Daytime**

croscarmellose sodium, crospovidone, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

### **Questions or comments?**

1-800-719-9260

### **Package/Label Principal Display Panel**

Daytime Relief

Compare to Vicks® DayQuil® Severe active ingredients

Non-Drowsy

daytime

severe cold & flu

Acetaminophen, Phenylephrine HCl,

Dextromethorphan HBr, Guaifenesin

Pain Reliever/Fever Reducer, Cough Suppressant, Expectorant, Nasal Decongestant

Alcohol Free/Antihistamine Free

Max Strength

actual size

32 Caplets

Nighttime Relief

Compare to Vicks® NyQuil® Severe active ingredients

nighttime

severe cold & flu

Acetaminophen, Phenylephrine HCl,

Doxylamine Succinate, Dextromethorphan HBr

Pain Reliever/Fever Reducer, Cough Suppressant, Antihistamine, Nasal Decongestant

Alcohol Free

Max Strength

actual size

16 Caplets



EXP. LOT NO.

3 70030 14527 0

OPEN OTHER END

Nighttime Severe Cold & Flu	Daytime Severe Cold & Flu												
<p><b>Drug Facts</b></p> <p><b>Active Ingredients (in each caplet)</b></p> <p>Acetaminophen 325 mg.....Pain reliever/fever reducer</p> <p>Dextromethorphan HBr 10 mg.....Cough suppressant</p> <p>Doxylamine succinate 6.25 mg.....Antihistamine</p> <p>Phenylephrine HCl 5 mg.....Nasal decongestant</p> <p><b>Uses</b> ■ temporarily relieves common cold/flu symptoms:</p> <ul style="list-style-type: none"> <li>■ nasal congestion ■ sinus congestion and pressure ■ headache</li> <li>■ cough due to minor throat and bronchial irritation ■ sore throat</li> <li>■ coughs help you sleep ■ minor aches and pains ■ fever</li> <li>■ runny nose and sneezing ■ reduces swelling of nasal passages</li> <li>■ temporarily restores free breathing through the nose ■ fever</li> <li>■ temporarily restores free breathing through the nose</li> <li>■ promotes nasal and/or sinus drainage</li> </ul> <p><b>Warnings</b></p> <p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4,000 mg of acetaminophen in 24 hours ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product ▼</p>	<p><b>Drug Facts</b></p> <p><b>Active Ingredients (in each caplet)</b></p> <p>Acetaminophen 325 mg.....Pain reliever/fever reducer</p> <p>Dextromethorphan HBr 10 mg.....Cough suppressant</p> <p>Guaifenesin 200 mg.....Expectorant</p> <p>Phenylephrine HCl 5 mg.....Nasal decongestant</p> <p><b>Uses</b> ■ temporarily relieves common cold/flu symptoms:</p> <ul style="list-style-type: none"> <li>■ nasal congestion ■ sinus congestion and pressure ■ headache</li> <li>■ cough due to minor throat and bronchial irritation ■ sore throat</li> <li>■ minor aches and pains ■ reduces swelling of nasal passages</li> <li>■ temporarily restores free breathing through the nose ■ fever</li> <li>■ promotes nasal and/or sinus drainage ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passage ways of bothersome mucus and make coughs more productive</li> </ul> <p><b>Warnings</b></p> <p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4,000 mg of acetaminophen in 24 hours ■ with other drugs containing acetaminophen ▼</p>												
<p><b>Drug Facts (continued)</b></p> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash. If a skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Sore throat warning:</b> If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.</p> <p><b>Do not use</b> ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. ■ If you have ever had an allergic reaction to this product or any of its ingredients.</p> <p><b>Ask a doctor before use if you have</b> ■ liver disease ■ diabetes ■ heart disease ■ high blood pressure ■ thyroid disease ■ cough that occurs with too much phlegm (mucus) ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema ■ trouble urinating due to an enlarged prostate gland</p> <p><b>Ask a doctor or pharmacist before use if you are</b> ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin</p> <p><b>When using this product</b> ■ do not use more than directed ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, and tranquilizers may increase drowsiness</p> <p><b>Stop use and ask a doctor if</b> ■ you get nervous, dizzy or sleepless ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ redness or swelling is present ■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition. ▼</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash. If a skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Sore throat warning:</b> If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.</p> <p><b>Do not use</b> ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. ■ If you have ever had an allergic reaction to this product or any of its ingredients.</p> <p><b>Ask a doctor before use if you have</b> ■ liver disease ■ diabetes ■ heart disease ■ high blood pressure ■ thyroid disease ■ cough that occurs with too much phlegm (mucus) ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ trouble urinating due to an enlarged prostate gland</p> <p><b>Ask a doctor or pharmacist before use if you are</b> taking the blood thinning drug warfarin</p> <p><b>When using this product</b> do not use more than directed</p> <p><b>Stop use and ask a doctor if</b> ■ you get nervous, dizzy or sleepless ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ redness or swelling is present ■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition. ▼</p> <p>If pregnant or breast-feeding, ask a health professional before use. ▼</p>												
<p><b>Drug Facts (continued)</b></p> <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. <b>Overdose warning:</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical. Braduats as well as for children even if you do not notice any signs or symptoms.</p> <p><b>Directions</b> ■ take only as directed - see overdose warning ■ do not exceed 4 doses per 24 hrs</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>adults &amp; children 12 yrs &amp; over</td> <td>2 caplets with water every 4 hrs</td> </tr> <tr> <td>children 4 to under 12 yrs</td> <td>ask a doctor</td> </tr> <tr> <td>children under 4 yrs</td> <td>do not use</td> </tr> </table> <p><b>Other information</b> ■ store at 20-25°C (68-77°F)</p> <p><b>Inactive ingredients</b> croscarmellose sodium, croscarmellose, FD&amp;C blue no. 1 aluminum lake, FD&amp;C blue no. 2 aluminum lake, FD&amp;C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, polyvinylpyrrolidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide</p> <p><b>Questions or comments?</b> 1-800-719-9260</p>	adults & children 12 yrs & over	2 caplets with water every 4 hrs	children 4 to under 12 yrs	ask a doctor	children under 4 yrs	do not use	<p><b>Drug Facts (continued)</b></p> <p>Keep out of reach of children. <b>Overdose warning:</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p><b>Directions</b> ■ take only as directed - see overdose warning ■ do not exceed 4 doses per 24 hrs</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>adults &amp; children 12 yrs &amp; over</td> <td>2 caplets with water every 4 hrs</td> </tr> <tr> <td>children 4 to under 12 yrs</td> <td>ask a doctor</td> </tr> <tr> <td>children under 4 yrs</td> <td>do not use</td> </tr> </table> <p><b>Other information</b> ■ each caplet contains: sodium 4 mg ■ store at 20-25°C (68-77°F)</p> <p><b>Inactive ingredients</b> croscarmellose sodium, croscarmellose, FD&amp;C blue #2 aluminum lake, FD&amp;C red #40 aluminum lake, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, polyvinylpyrrolidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide</p> <p><b>Questions or comments?</b> 1-800-719-9260</p>	adults & children 12 yrs & over	2 caplets with water every 4 hrs	children 4 to under 12 yrs	ask a doctor	children under 4 yrs	do not use
adults & children 12 yrs & over	2 caplets with water every 4 hrs												
children 4 to under 12 yrs	ask a doctor												
children under 4 yrs	do not use												
adults & children 12 yrs & over	2 caplets with water every 4 hrs												
children 4 to under 12 yrs	ask a doctor												
children under 4 yrs	do not use												

Distributed by:  
Perrigo  
Allergan, MI 48010

GLUTEN FREE

**PARENTS:**  
Learn about teen medicine abuse  
www.StopMedicineAbuse.org

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

These products are not manufactured or distributed by Perrigo & Gamble, distributor of Vicodin®/Dagguib® Severe and Vicodin®/Dagguib® Severe.

CONVENIENT RECLOSING TAB

## BASIC CARE DAYTIME NIGHTTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-7499
--------------	----------------	--------------------	---------------

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0113-7499-72	1 in 1 CARTON; Type 0: Not a Combination Product	01/16/2019	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
--------	------------------	------------------------

Part 1	8 BLISTER PACK	16
Part 2	16 BLISTER PACK	32

Part 1 of 2

BASIC CARE NIGHTTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl tablet, film coated

Product Information

Route of Administration	ORAL
-------------------------	------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L5Y5
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 CARTON		
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341		

## Part 2 of 2

### BASIC CARE DAYTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

## Product Information

Route of Administration	ORAL
-------------------------	------

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	RED	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19 mm
<b>Flavor</b>		<b>Imprint Code</b>	L922
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16 in 1 CARTON		
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/16/2019	

**Labeler** - L. Perrigo Company (006013346)

Revised: 11/2020

L. Perrigo Company